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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,982	08/26/2003	Paul S. Kaytes	01313.US1	3612
25533	7590	01/05/2006	EXAMINER	
PHARMACIA & UPJOHN 301 HENRIETTA ST 0228-32-LAW KALAMAZOO, MI 49007			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/647,982	Applicant(s) KAYTES ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the claims in improper Markush format. See Ex parte Markush, 1925 C.D.

126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the detection of distinct target molecules, i.e. distinct polymorphisms.

A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-56, drawn to methods for diagnosing a propensity for schizophrenia by detecting a haplotype consisting of the polymorphic sites 601 and 2106, classified in Class 435, subclass 6.
- II. Claims 1-56, drawn to methods for diagnosing a propensity for schizophrenia by detecting a haplotype consisting of the polymorphic sites 194 and 2106, classified in Class 435, subclass 6.
- III-XXVII. Claims 1-56, drawn to methods for diagnosing a propensity for schizophrenia by detecting a haplotype consisting of one of the polymorphic sites set forth in (3)-(25) of claim 1 or (3)-(27) of claim 29, classified in Class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-XXVII are drawn to patentably distinct method, each requiring the detection of distinct haplotype. Each polymorphic site within SEQ ID NO: 1 and each combination of polymorphisms is chemically and structurally distinct from one another. For example, a polymorphism at position 601 of SEQ ID NO: 1 is chemically, structurally and functionally distinct from a polymorphism at position 194 of SEQ ID NO: 1. Further, each haplotype is distinct from the other because the haplotypes consist of structurally distinct polymorphisms and each haplotype has a different effect. As set forth in the specification, each haplotype is present in populations of affected schizophrenia individuals and in control populations at different frequencies. For instance, with the S1(194)/S4 (1038)haplotype, the A/C polymorphisms were more prevalent in affected individuals as compared to the control individuals, while for the S6(2106)/S4(1038) haplotype, the A/G alleles were more prevalent in affected individuals as compared to the control individuals. Thereby, the effect of the S4 allele varies depending on whether the allele is considered together with the S1 allele or with the S6 allele. Similarly, with the S1/S4 haplotype, the A/C polymorphisms were more prevalent in affected individuals as compared to the control individuals, while for the S1/S2 haplotype, the G/G alleles were more prevalent in affected individuals as compared to the control individuals. Thereby, the effect of the S1 allele varies depending on whether the allele is considered together with the S4 allele or with the S2 allele. It is expected that each of the haplotypes will also be present in other disease populations and control populations at varying frequencies. Accordingly, each of the claimed methods for detecting a particular haplotype or combination of haplotypes is considered to be patentably distinct

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from one another. In response to the restriction requirement, Applicants should state the particular haplotype or combination of haplotypes that is elected.

4. These inventions are distinct for the reasons given above and have acquired a different status in the art as recognized divergent subject matter. Further, a search for inventions I-XXVII require different keyword and sequence searches that are not co-extensive. For example, a search for the methods which detect the polymorphisms at positions 601 and 2106 would require different keyword and sequence searches as compared to a search for methods which detect the polymorphisms 194, 1038 and 2185. Additionally, a finding that the method of invention I is novel and unobvious would not necessarily extend to a holding that the method of invention II is also novel and unobvious. Similarly, a finding that the methods of invention I were known or would have been obvious would not necessarily extend to a holding that the methods of invention II were also known and obvious. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

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a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
December 28, 2005


CARLA J. MYERS
PRIMARY EXAMINER